IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CYNTHIA DIBARTOLO, Plaintiff,	§	
v.	§	CASE #: _____
ABBOTT LABORATORIES, Defendant.	§	JURY TRIAL DEMANDED

COMPLAINT

COMES NOW, Cynthia DiBartolo, a citizen of New York and member of the Bar of this Court, and files this Complaint against Abbott Laboratories seeking monetary damages, because as a result of taking Abbott's blockbuster drug Humira, Ms. DiBartolo has had a significant portion of her tongue cut out to remove a cancerous tumor. Abbott knew about this risk of cancer before Ms. DiBartolo took the drug, but did not warn about that risk until two years after her life-threatening, permanently disabling, terrifying and dramatically life-altering surgery. Pleading further, Ms. DiBartolo would show the Court and Jury the following:

Nature of the Case

1. As noted in the introductory paragraph, this is a New York, diversity, products liability/personal injury case arising out of Cynthia DiBartolo's life altering, Humira-induced tongue cancer. Although Abbott had plenty of information about the risk of "non-melanoma skin cancers" before Ms. DiBartolo ever took their drug, at the time she took the drug, there was no warning whatsoever to alert her or her physician that the drug could cause such cancers.

2. Plaintiff Cynthia DiBartolo was prescribed Abbott's blockbuster drug "Humira" to treat psoriasis. Ms. DiBartolo received her first dose of Humira in November of 2008, followed by bi-monthly injections until April 2009, when her dentist discovered a mass on her tongue that was later diagnosed as squamous cell carcinoma. She alleges that Humira caused the cancer and that

Abbott, *inter alia*, failed to adequately warn about this risk at that time. However, in March 2011, at the insistence of the FDA, Abbott promulgated a warning, alerting both physicians and their patients – particular those patients, like Ms. DiBartolo, who had a history of light treatments with psoriasis – that they "should be examined for the presence of NMSC (non-melanoma skin cancer) prior to and during treatment with Humira." This was too little/too late for Ms. DiBartolo.

Parties

3. Plaintiff Cynthia DiBartolo is a resident and a citizen of New York, New York.

4. Defendant Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois and maintains its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. If necessary, Abbott may be served with process by serving its registered agent, Laura J. Schumacher, 100 Abbott Park Road, Abbott Park, Illinois 60064. However, the undersigned counsel are involved in other litigation against Abbott on behalf of Humira claimants, and believe that Abbott's counsel will accept service.

Jurisdiction and Venue

5. Diversity jurisdiction is proper under 28 U.S.C. § 1332, because Abbott Laboratories is an Illinois corporation, is headquartered in Abbott Park, Illinois, and Cynthia DiBartolo is a resident of New York, New York. The amount of damages exceeds $75,000, exclusive of interest and costs. The purchase, delivery and use of Humira by Ms. DiBartolo occurred in New York, and her damages were incurred here. Therefore, venue is appropriate in this forum under 28 U.S.C. § 1391.

Facts

This suit has been necessitated by virtue of the following facts which are pled with some specificity in light of Abbott's post *Twiqbal* strategy[1] of filing 12(b)(6) motions to dismiss in every federal Humira case.

Humira and the other "Tumor Necrosis Factor" Blockers

6. "Tumor Necrosis Factor" [hereinafter "TNF"] is a naturally occurring substance in the human body. TNF is related to the workings of the body's immune system. There is a class of biologic drugs known as TNF-alpha blockers. The first two on the US market were Remicade and Enbrel. The third was Humira which was initially "launched" in 2003 and has since become a multi-billion dollar, company-changing drug for Abbott.

7. Although there are certainly some differences, generally speaking, the TNF blocker class of "biologic" drugs has the same presumed mode of action and the same general safety profile. Indeed, in its regulatory filings, and in its competitive and promotional activities, Abbott has specifically tried to capitalize on this by suggesting that Humira has very similar effects like Enbrel and Remicade have in human beings.

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[1] We realize that this pleading is more detailed than the "short plain complaint" that suffices under the traditional notions of Rule 8 "notice pleading." However, in at least four federal Humira products liability cases that have been filed since *Twombly* and *Iqbal* were decided, Abbott has filed motions to dismiss instead of answers. *Mohr v. Targeted Genetics, Inc.*, 690 F.Supp.2d 711 (C.D. Illinois 2007)(allegations of Humira-induced histoplasmosis); *Wendell v. Johnson & Johnson,* 2010 WL 2465456 (N.D. Calif., June 14, 2010); *Murthy v. Abbott Laboratories*, (S.D. Tex.)[4:11-cv-00105-KPE]; *Anderson v. Abbott Laboratories*, (N.D. Tex.)[3:11-cv-01825-L]. The undersigned represents the plaintiffs in the *Murthy* and *Anderson* cases. In those cases, *inter alia*, Abbott seeks dismissal because it contends that the plaintiffs failed to negate its "learned intermediary" affirmative defense in the Complaints. It is, thus, Abbott's litigation strategy that compels this prolix pleading, including the fulsome allegations regarding its pervasive influence over the fields of rheumatology and dermatology and its extensive efforts to circumvent the traditional doctor/patient relationship.

8. Because of their mode of action in the human body, there is a "biologically plausible" explanation for the causal association between Humira, and the other TNF-alpha blockers, and cancer. Abbott's company witnesses have conceded as much in depositions in the *Jones*[2] case pending in Memphis, Tennessee.

Mass Marketing of a Blockbuster Medication

9. Humira, the generic name of which is "ADALIMUMAB,"[3] was not developed by Abbott Laboratories R&D. Rather, the compound which began with the research code D2E7 was owned by a company called Knoll Pharmaceuticals. Abbott acquired the rights to this drug in March of 2001 when it purchased Knoll. Amazingly, it then managed to "fast track" the New Drug Application ["NDA"] for Humira and received FDA approval to market the drug in the record time of five months. Abbott launched Humira[4] worldwide in 2003 to treat rheumatoid arthritis [hereinafter "RA"]. Subsequently, it "launched" five other "indications" for this drug, including psoriasis, which Cynthia DiBartolo has had off and on since she was quite young.

10. Even though two other major biologic TNF blockers, *i.e.,* Enbrel and Remicade, had already been approved for RA, Abbott expected Humira to be a "blockbuster" drug for the company. A "blockbuster" drug is commonly defined either (a) as a drug that generates more than $1 billion

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[2] *Freddie Jones, et al. v. Abbott Laboratories*, (W.D. Tenn.)[2:07-cv-02120-SHM].

[3] Generic drug names are interesting. The first three letters, ADA, were selected by Abbott. The "LIM" means that it is an inflammation mediator, the "U" signifies that it was derived from human cells, and the "MAB" stands for a monoclonal antibody.

[4] As Stanford business researchers have noted, "The HUMIRA launch was global in scope, and Abbott Laboratories considered global coordination to be a critical success factor for bringing a blockbuster drug to market." Exhibit A, Stanford Graduate School of Business, ABBOTT LABORATORIES AND HUMIRA: LAUNCHING A BLOCKBUSTER DRUG, Case O1T-44 at p.2n.4. Condensed (6/25/2005)(written in cooperation with Abbott personnel)[hereinafter "ABBOTT BLOCKBUSTER"].

in annual sales, or (b) "at its peak sales level, typically account for 20%-30% of that company's total sales. . . . Blockbusters are, therefore, often products that define a company."[5]

11. By either of these measures, Humira has been a "blockbuster" for Abbott. Humira first received approval from the U.S. Food and Drug Administration [FDA] on December 31, 2002 for the treatment of moderately to severely active RA. Humira was launched in the United States at the beginning of 2003 and reached sales of approximately $246 million in its first year alone. By 2005, sales had reached $1.4 billion. Since that time, sales revenues have continued to grow. The 2009 worldwide sales were approximately $5.5 billion. By 2010, they had increased to approximately $6.5 billion. In 2011, they are projected to be more than $8 billion.

12. On October 19, 2011, Abbott issued a press release announcing that it would "separate into two leading companies." One of these will be its "research-based pharmaceutical company." The $8 billion in Humira sales for 2011 are nearly half the revenues of the new entity.

13. Abbott achieved these financial successes by clever marketing focusing, not only on the doctors who prescribe the medication, but on the patients who pay for it and use it. From the start, according to one of its top marketing executives, "our overriding goal in going to market was to be exquisitely patient-friendly and doctor-supportive."[6]

"Doctor Supportive"

14. Abbott has certainly been true to its plan of being "doctor supportive." At the time of the launch, only 10% of the patients in the potential market were taking biologics. Thus, as an Abbott executive later explained, "for HUMIRA to be focused only on stealing from that 10 percent

[5] ABBOTT BLOCKBUSTER, *supra*, quoting *The Blockbuster Drug Outlook*, Reuter's Business Insight, *Datamonitor*, April 2001.

[6] A BBOTT BLOCKBUSTER, *supra* at p. 13.

didn't make sense. The biggest opportunity was to go after the 85 to 90 percent of patients who were potentially eligible but not on a biological treatment" by *educating physicians*.[7]

15. Abbott's physician education program included an initial $4.5 million endowment to attract medical students to go into the small field of rheumatology, an Abbott Scholar Program, and the retention of "Key Opinion Leaders" ["KOLs:] to speak on behalf of Abbott and Humira. On information and belief, it has also ghost-written medical articles, or paid agencies to create them for authors. Abbott's money has given it a pervasive influence on the entire field of rheumatology which is the medical specialty that commonly diagnoses and treats RA, the first approved indication for Humira.

16. On information and belief it is also alleged that Abbott has been equally accommodating to dermatologists in anticipation of, and in the wake of, its 2008 launch for the plaque psoriasis indication. One way that Abbott permeates a field of medicine is to hire numerous physicians across the country to participate in so called "phase III clinical trials" of the medicine. The physicians in these trials are normally specialists who treat the conditions in issue as part of their regular practice. They are paid one amount of money to recommend that the patient be screened for treatment with Humira, and a higher amount of money if they actually enroll the patient in the trial, and even higher if they keep them in the trial.

17. Needless to say, these financial patient bounties provide incentives, perhaps on a subconscious level but real nonetheless, to skew the "informed consent" discussion in favor of the benefits of Humira, at the expense of the risks. The clinical trials have catchy names derived from acronyms. For example, Abbott's trial with dermatologists prescribing Humira for a long period of time to patients, like Cynthia DiBartolo, with psoriasis, is called "REVEAL."

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[7] ABBOTT BLOCKBUSTER, *supra* at p. 16, quoting interview with Abbott executive.

18. At the present time it is not known whether Abbott enrolled Cynthia DiBartolo's prescribing physician, Dr. James Jian Cui in REVEAL, or whether and to what degree it provides other encouragement or financial incentives to him to prescribe Humira as a first line treatment for a brand new patient. Hopefully, reasonable discovery in this case will "*reveal*" the whole truth.

"Patient Friendly"

19. From the start, Abbott has also undertaken significant efforts to "educate" patients about their disease states, thereby to empower them to "self-diagnose" and then, of course, to "ask for" Humira. Abbott marketers know that in the vast majority of circumstances that a patient comes in to a medical office and "asks her doctor" about a medication she will receive a prescription for that medication. Abbott's Humira promotional activities *vis-à-vis* patients themselves involved significant direct-to-consumer ["DTC"] advertising, direct-to-consumer patient counseling and internet website promotion.

20. Abbott's DTC promotion of Humira illustrates the power of the well-known aphorism that a "picture is worth a thousand words." Communication specialists, including Abbott's marketing and advertising people, know that about 70% of the message that any audience receives comes from the *visual* images that they see. Abbott's DTC advertising sends consistent audio and visual messages about the *benefits*, but **inconsistent** messages about the risks of Humira. The following two pictures from Abbott's current psoriasis advertisement on its website, www.humira.com,[8] illustrate this.

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[8] Exhibit B hereto is the current, January 2012, screen shot of the first three pages of Abbott's website, www.humira.com. As the Court will see, there is a button that allows consumers to click and "view Humira TV Commercials." The following photos were captured from the TV commercial for psoriasis.

The language in the warning on the home page, "If using TNF blockers including HUMIRA, your chance of getting two types of skin cancer (basal cell and squamous cell) may increase" was

In the top picture, the message that is conveyed by the photograph of the happy patient with clear skin is reinforced by both (a) an audio "voice over" that says "in clinical trials, most adults saw 75% skin clearance" and (b) a text box on screen with the same message.

not on the labeling in late 2008 when Dr. Cui prescribed this medication for Cynthia DiBartolo. Interestingly, however, even now, this sentence is ameliorated by the one that follows it: "These types are generally not life-threatening if treated; tell your doctor if you have a bump."

The bottom/foregoing picture also conveys a message that people have clear skin and are happy when they take Humira. The FDA-mandated voice over chronicles a litany of dangerous side effects, but they are read fairly quickly and significantly occluded by music. Moreover, the text box depicted on the screen while the voice over says "Serious, sometimes fatal, events can occur, such as infections, lymphoma or other types of cancer" reads "See our ad in Fitness Magazine." Needless to say, although the benefit is quantified at 75%, the three-fold risk of cancer, also seen in clinical trial data, was not. Exhibit C hereto is a true and correct copy of the text of this video, as downloaded from Abbott's website.

21. Obviously, the inherent goal of this "patient friendly" advertising is, not only to persuade patients to "ask for" Humira by name, but to discount the risks and reinforce the benefits that are touted by the prescriber. It is appalling in these circumstances that Abbott would seek to hide behind the shortcomings of the very "learned intermediaries" that it "details" to avoid liability to citizens like Cynthia DiBartolo with legitimate, permanently life-altering, Humira-induced injuries.

A Pattern of Delay

22. It is obvious from the foregoing that, to use words from an old song, Abbott undertakes significant efforts to "accentuate the positive" benefits of Humira – to both physicians and patients – while "eliminating [or minimizing] the negative" messages about Humira. But it also does something that is much worse.

23. FDA regulations require the drug manufacturer to add a warning – in the warnings section of the label – whenever there is a "reasonable association" between the drug and a dangerous side effect, and further state that "a causal relationship need not be established" before a warning is required, 21 C.F.R. § 201.80(e). Abbott has, with regard to all three of the major categories of

deadly side effects of Humira, *i.e.,* (a) cancer, (b) infections, and (c) neurological conditions, delayed warnings until the FDA absolutely forces it to implement them.

24. Its delay of a warning about non-melanoma skin cancers until March of 2011, two years after Cynthia DiBartolo nearly had her face literally cut in two, is part and parcel of this pattern and practice.

Humira and Squamous Cell Carcinoma

25. Almost all forms of cancer are "multi-factorial," which is to say that there are frequently several interrelated causative factors that contribute to any person's cancer. It is for this reason that the common practice in oncology, as elsewhere in medicine, is for physicians to utilize a "differential diagnosis" to list all potential causes of a cancer, and then, if necessary or desirable, to determine which factor, or factors, contribute in a substantial or material way to the disease process.

26. However, it is well known that some medications, and other dangerous drugs, chemicals and substances, are associated with higher incidences of specific types of cancer. Humira's demonstrated association with a rare form of lymphoma known as HSTCL is an excellent example of this.

27. Squamous cell carcinoma (SCC) is a well-known form of non-melanoma skin cancer (NMSC). It arises in the squamous cells that make up most of the skin's upper layers called the epidermis. Squamous cell carcinomas may occur on all areas of the body including the mucous membranes and genitals, but are most common in areas frequently exposed to the sun, such as the rim of the ear, lower lip, face, bald scalp, neck, hands, arms and legs.

28. It is far less likely to happen in place like the tongue, that has not been exposed to sunlight on a regular basis. Therefore, when one attempts to discern the etiology of a tongue cancer, like Cynthia DiBartolo's, it is much more likely that a carcinogen like Humira could be the culprit.

29. Even before Humira was approved by the FDA, Abbott had evidence that Humira was associated with skin cancer. On information and belief, patients taking Humira in pre-marketing clinical trials were three times more likely to develop both non-melanoma and melanoma skin cancer than the general population. Moreover, in these same trials patients taking Humira were more likely to get skin cancer than patients taking placebo.

30. Because of the small number of patients involved in clinical trials, it is well recognized within the pharmaceutical industry that adverse event reports received from actual patients after the drug has been released into market are a major, and important source of safety information. The FDA's MedWatch program was set up to monitor this information.

31. Although anyone can file a report with the company or the FDA, the majority of such reports are filed by concerned physicians who suspect that a prescription drug is associated with their patient's adverse event.

32. Following Humira's approval by the FDA, Abbott received no less than nine MedWatch Reports from healthcare providers notifying Abbott that they had Humira-treated patients whose skin cancer was "probably" related to Humira injections. It is well known that adverse event reports represent only a tiny fraction of the actual number of adverse events occurring in the patient population. Therefore, the number of real world skin cancers in association with Humira was likely to be between 90 and 900. Therefore, it is probable that these reported cases were just the tip of the iceberg of actual skin cancer cases related to Humira injections.

33. In November of 2005, researchers from the Division of Immunology and Rheumatology at Stanford University School of Medicine published the results of a large cohort study in the peer-reviewed *Journal of Rheumatology*. Exhibit D. The researchers found that RA patients prescribed biologics–including Humira–were at increased risk for NMSC. This finding was supported by a 2007 study published in *Arthritis & Rheumatism* that found biologic therapy, including Humira, was associated with an increased risk for developing NMSC. Exhibit E.

34. Moreover, as noted above, Abbott's witnesses have already conceded in other litigation that there is a biologically plausible explanation for a causal link between "**tumor** necrosis factor" antagonists, like Humira, and cancer.

35. Taken together, the biological plausibility, pre-marketing clinical trial data, the post-marketing adverse event reports, and the studies published in two well-respected, peer-reviewed, scientific journals were strong evidence of an increased risk of skin cancer in patients taking Humira. This should have prompted Abbott to include a strong skin cancer warning in their label well before 2008 when a New York dermatologist prescribed this medication to Cynthia DiBartolo to treat her psoriasis.

36. On information and belief, employees within Abbott were aware of this increased skin cancer risk, yet the company failed to pass this information on to patients and doctors. Sadly, this was not done until 2011, much too late for Cynthia DiBartolo.

Risk Evaluation and Mitigation Strategies

37. Humira may help some people with psoriasis. In fact, it cleared up Cynthia DiBartolo's psoriasis. However, the price to pay was far too high, because although Ms. DiBartolo experienced good control over her symptoms while on the drug, she had no idea whatsoever that the medication which was helping her cope with her psoriasis was also causing her to contract a life-

threatening and disfiguring cancer. Had she been properly warned, she would not have accepted that risk. Had Dr. Cui been properly instructed about the need to carefully monitor his patient throughout her therapy on Humira, he may well have caught the incipient cancer before its deadly growth necessitated radical surgery. Dr. Cui well also may have chosen not to prescribe it at all.

38. Although physicians prescribe medications, it is patients who have the ultimate authority to decide whether or not to put those chemicals into their bodies. Humira is an extremely potent drug that compromises the body's natural immune system, thereby exposing the patients to an increased risk of (a) cancer, (b) infections, and (c) neurological damage. People who take it – and, indeed, the people who recommend it and prescribe it for injection by their patients, deserve to be fully informed and adequately warned about the risks, and instructed about what they need to do to "mitigate" that risk.

39. In this regard, it is significant that, in the Spring of 2008, at or about the same time that Abbott was launching Humira for psoriasis, the FDA exercised new statutory authority conferred via the 2007 amendments to the Food Drug and Cosmetic Act, to require Abbott to implement a "Risk Evaluation and Mitigation Strategy" [REMS]. On September 4, 2008, one month before Dr. Cui prescribed Humira to Cynthia DiBartolo, the FDA issued a release directing Abbott to implement a REMS on Humira. Although the principal focus of that REMS was "histoplasmosis" and other opportunistic infections, a legally significant component was the requirement that *patients be directly warned* via FDA Patient Medication Guides.

40. Thus, Abbott could, and should, have promulgated a Patient Medication Guide that would specifically call Cynthia DiBartolo's attention to the risk of developing Humira-induced skin cancer. But it failed to do so.

41. The bottom line is that, because of the dangerous side effects of Humira, it is extremely important that *both* physicians and patients be fully informed – not only about the potential benefits of the drug, but also about the risks of side effects. Human decency, the common law of New York, and the FDA all require it. But in this case, neither Cynthia DiBartolo nor her physicians were warned in any meaningful or legally adequate manner about the risk of skin cancer prior to or during the time she was using Humira.

Anticipating Abbott's Learned Intermediary Defense

42. The "learned intermediary" doctrine is a well-known, industry specific, *affirmative defense* in pharmaceutical cases in some jurisdictions. New York has recognized an early common law species of this defense. It would not, therefore, be surprising, for Abbott to attempt to plead and prove this defense. To do so, however, it would have to prove that it provided legally adequate warnings and instructions to Dr. Cui.

43. Contrary to a company willing to stand by its drug, Abbott has argued in the *Murthy* and *Anderson* cases, referenced *supra* note 1, that the plaintiff must anticipate and negate this affirmative defense to survive a 12(b)(6) motion to dismiss. It is because of Abbott's litigation strategy that this Complaint addresses this defense fact specifically, and that the allegations under this heading are laid out chapter and verse.

44. Although there are a couple of states that have statutory codifications of the learned intermediary doctrine, the only codification-like statement of the common law doctrine is contained in § 6(d) of the 1998 RESTATEMENT (THIRD) OF TORTS, which contains both a "rule" and an "exception." The "rule" is that warnings/instructions should be given, not only to the prescribing physician, but to all "health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." § 6(d)(1). The "exception" requires

warnings/instructions directly to "the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." § 6(d)(2). Included in this instance is when the medication is accompanied by a patient package insert or the manufacturer engages in use of mass media. *Id*. at comment *e*. Both of those circumstances are present in this case.

45. Although the New York Court of Appeals has not addressed the learned intermediary doctrine in many years, and has not ever mentioned this particular RESTATEMENT section, it has embraced RESTATEMENT (THIRD) § 3, which permits an inference of product defect from circumstantial evidence.[9] Therefore, when the time comes for the Court to make an *Erie* prediction,[10] it can safely predict, at minimum, that, if New York adheres to this doctrine at all, it will embrace the RESTATEMENT articulation of it.[11]

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[9] "New York has long recognized the viability of this circumstantial approach in products liability cases. . . . In this regard, New York law is consistent with the Restatement" *Speller ex rel. Miller v. Sears, Roebuck & Co.,* 100 N.Y.2d 38, 41, 790 N.E.2d 252, 254-55 (2003)(citing Restatement-Third, § 3).

[10] Judge Cogan in the Eastern District recently cited Restatement § 6(d) in predicting Rhode Island law and denying a drug company's motion in limine to exclude evidence or arguments that warnings should have been provided to "other health providers" besides the actual prescribing physician. *Hogan v. Novartis Pharmaceuticals Corp.*, 06 CIV. 0260 BMC RER, 2011 WL 1533467 (E.D.N.Y. Apr. 24, 2011).

This Court could also, of course, do the same thing that the federal court did in a recent New Mexico case and predict that, today the New York Court of Appeals would reject the doctrine in its entirety as being "outmoded and unpersuasive." *Rimbert v. Eli Lilly & Co.,* 577 F.Supp.2d 1174 (D.N.M. 2008), following lead of *State ex. rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 905 (2007), also cited by the *Hogan* court.

[11] Two state courts of last resort have specifically adopted § 6(d). *Larkin v. Pfizer, Inc.,* 153 S.W.3d 758, 770 (Ky. 2004)("now adopt Restatement (Third) of Torts: Products Liability § 6(d).); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Ne. 2000)("We adopt § 6(d) of the Third Restatement").

The New Jersey High Court has recognized a common law "direct-to-consumer" advertising exception. *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999). And, in neighboring

46. This is quite significant because the RESTATEMENT'S comments to § 6(d)(2) indicate that warnings should be required directly "to patients" – in circumstances like those presented here, (a) where the drug company uses direct-to-consumer advertising and Internet promotion to sell consumers on their medications, and/or (b) where, like here, the Government itself has recommended, or in this case, insisted upon, direct-to-consumer warnings.

47. Finally, it is significant that New York follows the "read and heed" presumption of comment *j* to RESTATEMENT (SECOND) OF TORTS, § 402A.[12] Therefore, under the law there is a presumption in the law that both Cynthia DiBartolo's physicians, and Ms. DiBartolo would have heeded an adequate warning and instructions to avoid or reduce the risk of skin cancer *if* Abbott had provided one to them. But the converse is equally true, *i.e.,* where, as here, there are no legally adequate warnings, the presumption becomes, in essence, a presumption of causation.

Humira: Cynthia's Nightmare

48. Cynthia DiBartolo is an attorney from New York City with a tremendous history of success in the financial industry working for firms such as Bear Sterns, Merrill Lynch and Smith Barney. Prior to her devastating experience with Humira, Ms. DiBartolo worked for Citigroup for almost 16 years, ironically, as a manager and director in Compliance Internal Control and Risk Management.

Connecticut, the Supreme Court has recognized six different common law exceptions to the doctrine, including over-promotion, at issue in this case. *Vitanza v. The Upjohn Co.,* 778 A.2d 829, 846-47 (Conn. 2001).

[12] *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329, 338 (S.D.N.Y. 2006)("Failure to warn law includes a presumption that 'a user would have heeded warnings if they had been given, and that the injury would not have occurred.'" *Accord Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 441 (S.D.N.Y. 1999). *See also In re Fosamax Products Liab. Litig.,* 688 F. Supp. 2d 259, 265 (S.D.N.Y. 2010).

49. Cynthia DiBartolo has been plagued by "the heartbreak of psoriasis" off and on through the years. For example, at one point in her life, she was a synchronized swimmer, and was embarrassed to have to deal with ugly outbreaks of psoriasis on her skin. She has had various treatments through the years, including light therapy. But her bout with psoriasis has not been constant. It has come and it has gone.

50. Psoriasis tends to flare up when a person is under stress. In late 2008, Cynthia DiBartolo was coping with work related stress. One of the physicians, who her insurance company covered, was New York dermatologist, Dr. Cui. Ms. DiBartolo saw him for the first time on or about November 5, 2008, and was immediately prescribed Humira in a dose of 40 mg[13] every other week. She took the injections continuously for about six months.

51. As noted above, Cynthia DiBartolo does not know at this point to what degree Dr. Cui was "detailed" or otherwise encouraged to prescribe Humira. Discovery will *reveal* that fact. However, because the approved "FDA indication" was for patients whom the physician had been unable to help with more traditional medications, it is extremely significant that, in his first visit with this patient, Dr. Cui pulled out the elephant gun. To the extent that the evidence shows this "off label" prescription, it is hereby alleged, on information and belief, that Abbott encouraged it. This is, of course, violative of FDA regulations and actionable under New York law.

52. On April 16, 2009, Cynthia DiBartolo saw her dentist, Dr. John Purpura, for a bonded tooth. While she was in the dentist's chair he noticed a raised, velvety, irregular white mass on the left side of her tongue and advised her to have it biopsied immediately. Based on his recommendation, she made the decision to discontinue the Humira injections.

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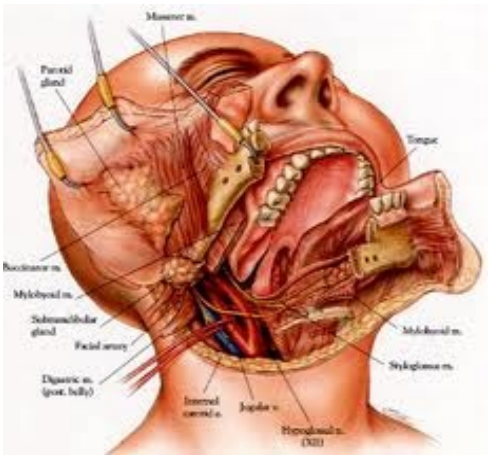
[13] For ease of administration, and the marketing benefits associated therewith, Abbott designed Humira in a "one size fits all" injectable pen. The 40 mg dose is unreasonably dangerous for a petite woman like Cynthia DiBartolo who stands only 4' 11" tall.

53. A surgical biopsy of the tongue mass was performed on April 20, 2009. In addition, Cynthia DiBartolo underwent a flexible laryngoscopy, where an endoscope was inserted through her nose and passed into the throat so that her voice box and throat could be examined.

54. On April 22, 2009, Cynthia DiBartolo received her diagnosis from Dr. David Kutler, an Otolaryngologist with New York Presbyterian Hospital: Malignant Neoplasm of the Tongue - Squamous Cell Carcinoma. The physician's recommendation: radical cancer surgery and treatment. Because this is an extremely disfiguring and disabling surgery, Ms. DiBartolo explored numerous medical options before finally settling on a course of treatment. But, in view of the aggressive nature of the cancer in her tongue, she did so quickly.

55. One possibility was "robotic" surgery, which might hold the promise of the least amount of disfigurement and functional disability. She investigated that type of surgery at the University of Pennsylvania, but, after exploratory surgery, she was advised that the mass was too large, and that she was not a candidate for robotic surgery.

56. The surgical approach used by most doctors Cynthia DiBartolo consulted was, in her estimation, "barbaric." It is called a "mandibulotomy" and involves cutting the face, lip and jaw literally in half in order to provide maximum exposure to the oral cavity in order to get to the tongue mass. Needless to say, it leaves the patient disfigured and with limited opportunities for functionality. Juxtaposition of the following 2008 photograph of Ms. DiBartolo with a medical illustration of the surgery demonstrates why she decided she would rather choose to live whatever time she had left with independence and dignity. Ms. DiBartolo refused to allow herself to be a burden to her family, nor succumb to the effects of such an insidious place to have developed cancer.



57. With the help of her father, a dentist in New York City, Cynthia DiBartolo aggressively searched for a hospital and team of surgeons who would agree to try to perform the surgery without dissecting and disfiguring her face. After numerous rejections, they found Drs. Daniel Buchbinder and Mark Urken at Beth Israel Medical Center. Following multiple tests, scans, scopes, and discussions about the course of treatment, surgery was scheduled for May 18, 2009, at Beth Israel Medical Center Head and Neck Cancer Institute.

58. Prior to admission, Cynthia DiBartolo quickly got her personal affairs in order, assigning power of attorney to a good friend and preparing for the unknown outcome of her surgery and the possibility of not being able to ever speak again, if she made it through the surgery at all.

59. Additionally, prior to surgery, Cynthia DiBartolo was asked to sign a consent form agreeing to allow her doctors to perform a mandibulotomy under sedation if they thought it was absolutely necessary. Thus, when she was placed under anesthesia, Ms. DiBartolo had no idea whether or not she would wake up with an intact face.

60. Happily, she had excellent surgeons and a successful operation. Surgeons Urken and Buchbinder, in a day-long surgery, removed a substantial portion of Cynthia DiBartolo's tongue

(partial glossectomy), and performed a radical neck dissection to remove all of the lymph nodes and tissue that were likely to be malignant. Her tongue also had to be reconstructed using microsurgical free flap surgery, where arteries, veins and tissue from her left arm were used in the reconstruction. When Ms. DiBartolo awoke from the surgery, although she could not speak, she was relieved to discover that she still had a face, and, in her words, "was not a monster."

61. Following eight days of hospitalization, Cynthia DiBartolo underwent three blood transfusions and experienced serious post-surgical respiratory complications. She felt like she was drowning, at one point coded, and even as she struggled to communicate, wrote on a board. "Daddy, am I dying?" She finally stabilized and was able to breath without the aid of a respirator and, on May 28, 2009, was discharged. Ms. DiBartolo immediately began daily speech therapy under the counseling of Jacqueline Mojica at Beth Israel Medical Center (and then speech pathologist, Dr. John Haskell). Although it is impaired, she has regained her speech. She was also treated and continues to be treated by Dr. Israel Klein for depression.

62. Cynthia DiBartolo's medical problems did not end with the 2009 surgeries. On November 1, 2010, Cynthia was once again admitted to Beth Israel Medical Center for yet another surgery to remove another mass on the left side of her tongue diagnosed as a non-malignant neuroma.

63. In March 2011, Cynthia DiBartolo began neurologic testing due to seizure-like episodes that she is experiencing sometimes as often as five times a day. She also continues with weakness on her left side, has difficulty speaking, and has sharp stabbing pains in the neck as a result of the radical neck dissection.

64. At the age of 49, Cynthia DiBartolo is now on long-term disability due to her permanent speech impairment as a result of her Humira-induced tongue cancer. Her life will never

be the same, personally or professionally. Not only is her speech impaired, she continues to have ongoing chronic pain, difficulty eating and swallowing, periodic dysphagia, permanent impairment of her lymphatic system on the left side from the radical neck dissection, and she has to regularly perform manual lymphatic drainage to remove the fluids that have built up. She has limited range of motion in her left hand and arm, impaired hearing in her left ear, and scarring in numerous areas. Ms. DiBartolo's cancer is currently in remission, yet she still undergoes periodic PET/CT scans to ensure there has been no reoccurrence of cancer. She will have to continue to receive these scans regularly until the fifth anniversary of her cancer surgery.

Abbott's Initial Silence – and Belated Warning

65. In November 2008, when Cynthia DiBartolo began her Humira injections, Abbott said very little about the risk of non-melanoma skin cancers. In fact, they repeated again in their labels, literature, and medication guides that "the potential role of TNF blocking therapy in the development of malignancies is *not known*."

66. However, in March 2011, at the insistence of the FDA, Abbott decided to tell a different story. A major change was made to the label, specifically warning psoriasis patients:

> **All patients, and in particular psoriasis patients with a history of PUVA treatment should be examined for the presence of NMSC (non-melanoma skin cancer) prior to and during treatment with Humira.**

67. Cynthia DiBartolo was certainly not at high risk for cancer, particularly oral cancer. She does not drink significantly and she has never smoked. She has suffered from psoriasis since she was a little girl and tried a variety of treatments, including light therapy. Yet Abbott failed to warn her or her doctor that Humira injections would suddenly put her in a high-risk category for non-melanoma skin cancer, and, particularly, squamous cell carcinoma, a highly aggressive, potentially fatal condition. This warning was too late for Ms. DiBartolo.

The Indomitable Ms. DiBartolo

68. Cynthia DiBartolo was once an active, productive young woman with an incredible future ahead of her – until Humira. Her life has, in many respects, been decimated by Humira. For that she deserves substantial compensation. On the other hand, what the Court and Jury will see when this case goes to trial is that Ms. DiBartolo is not a quitter.

69. Rather, Cynthia DiBartolo is a courageous woman who has persevered and continues, in spite of the horrible consequences of her Humira injections, to have a positive outlook on life. She recently founded Tigress Financial Partners LLC, a MWOB (minority women owned business) boutique investment bank and licensed broker dealer. Part of her mission in doing so–other than the reality that because of her injuries she could no longer operate in the high paced, demanding world of corporate America–was to inspire head and neck cancer survivors to continue to "preserve as much quality of life as possible." In addition, on February 1, 2012, she will begin a two year term as Chairperson of the Board of the Greater NYC Chamber of Commerce.

Cause of Action

The foregoing facts give rise to legally cognizable claims against Abbott under the common and/or statutory law of New York as follows:

70. FIRST - STRICT LIABILITY. Plaintiff asserts a cause of action for strict products liability under the law of New York., or, if the Court chooses, Illinois law. Humira is "unreasonably dangerous" and/or "defective" under New York law. Additionally product liability theories include design defect, failure to warn, and misrepresentation.

71. SECOND - NEGLIGENCE. Defendant Abbott was negligent in the design and testing of the drug Humira, in the marketing and promotion of the drug, and in the collection and analysis of adverse event data, and said negligence was a proximate or legal cause of Plaintiff's

cancer. Therefore, Abbott is liable for negligence under the common law of New York and/or Illinois. As a direct and legal result of the negligence of Defendant and/or its agent(s), Plaintiff has sustained serious and permanent injuries including, but not limited to the removal of a portion of her tongue, and lymph nodes and tissue that were likely to be malignant; tongue reconstruction using arteries, veins and tissue from her left arm; mental anguish; loss of some capacity or ability to enjoy life as fully as before; expense of hospitalization; cost of medical, nursing care, and rehabilitation; loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and losses are continuing in nature as she will never regain her full speech abilities and will have to be routinely evaluated for the rest of her life to determine if there has been a reoccurrence of cancer.

72. THIRD - WARRANTY. Plaintiff relied, not only on the recommendations of her doctor, but also on the reputation and representations made by Abbott in its promotion of Humira, and she had the right to expect Abbott to stand behind its product and to bear the burden for any injuries she sustained as a result of her use of its product under the law of New York. Because Defendant Abbott has breached its warranty obligations under New York law, it is further liable to Plaintiff for her injuries.

Damages and Remedies

73. Plaintiff sues to recover all elements of compensable damages under New York law, to include compensation for her increased risk of further cancer in the future and the medical monitoring costs associated with such. The damages are in the millions of dollars. Additionally, she seeks appropriate prejudgment interest thereon, as provided by law.

74. If, as expected, the evidence at trial demonstrates Abbott engaged in willful and/or wanton conduct that evinces an utter indifference or conscious disregard for the safety of patients

like Plaintiff, then the Jury may, in its discretion, award punitive or exemplary damages, and should, in fact, do so.

Jury Demand

75. Plaintiff invokes her constitutional right to trial by jury.

Prayer for Relief

WHEREFORE, Plaintiff Cynthia DiBartolo prays that Defendant Abbott Laboratories be cited to appear and answer herein, and that upon the final trial of this case, a Final Judgment be entered by this Court in Plaintiff's favor against Defendant for such compensatory and punitive damages as are appropriate, plus interest and costs of litigation, and awarding such other and further relief as is just and proper.

Respectfully submitted,

PERDUE KIDD & VICKERY

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[Admission *Pro Hac Vice* to be sought by all counsel in accordance with Local Rule 1.3(c)]

Certificate of Courtesy Service

Once Abbott has answered, the CM/ECF system will effectuate service. However, a courtesy copy of this Original Complaint has been provided to the following counsel for Defendant Abbott Laboratories:

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